This responds to the December 14, 2005 Office Action in the above-identified application, in which the Examiner imposed a restriction requirement against claims 1-21 pending in the application, between:

- Claims 1-11, drawn to a transgenic rat and cells from said transgenic rat comprising CD4 (Group I);
- Claims 12 and 13, drawn to an assay identifying lentiviral ligand antagonist in CD4 transgenic rat by measuring HIV levels on PMBC (Group II);
- Claims 14-17 and 19, drawn to a method of identifying compounds that inhibit HIV infection in cells or rats measuring HIV levels (Group III);
- Claim 18, drawn to a method of identifying compounds that reduce infection by measuring symptoms (Group IV); and
- Claims 20 and 21, drawn to an assay identifying test compounds that interfere with lentivirus ligand binding to CD4 in cells (Group V).

In response, applicant elects Group I claims 1-11. Such election is WITH TRAVERSE.

The traversal is based on the fact that the stated grounds for the restriction do not comport with the requirements of the 35 USC 121, which requires that:

> **"[I]f two or more independent and distinct inventions are claimed in one application, the Director may require the application to be restricted to one of the inventions."**

This statute, nothwithstanding anything otherwise stated in the MPEP or Group 1600 policy documents, therefore requires that the subject matter of respective claims be both independent and distinct as a basis for legally permissible restriction.

Group I claims 1 and 3 are set out below for ease of reference:

> **"1. A transgenic rat, whose genome comprises at least one copy of a transgene encoding at least a portion of a CD4 protein sufficient for binding to gp120, wherein CD4 encoded by the transgene is expressed on PMBCs of the transgenic rat."**

"3. The transgenic rat of claim 2, wherein CD4 is human CD4."

Group II claim 12 requires:

"12. An assay for identifying a molecular antagonist compound, which interferes with a lentivirus ligand-CD4 receptor interaction, comprising the steps of:
(a) administrating the molecular antagonist compound to a transgenic rat of claim 1; and
(b) determining the level of interaction between the lentivirus ligand and CD4 receptor expressed on PMBCs of the transgenic rat, wherein a difference in the level of interaction between the lentivirus ligand and CD4 receptor expressed on PMBCs of the transgenic rat relative to that in a transgenic rat to which the compound was not administered indicates that the compound interferes with the lentivirus ligand and the CD4 receptor."
(emphasis added)

Group III claims 14 and 19 require:

"14. A method for identifying a compound which inhibits infection of a human cell by HIV-1, comprising
(a) administrating a test compound to a transgenic rat of claim 3 or contacting a cell thereof with the test compound; and
(b) determining the level of IV or gene product thereof in the transgenic rat or cell thereof of step (a),
wherein a lower level of HIV or gene product thereof in the transgenic rat or cell thereof of step (a) relative to that in a transgenic rat to which the test compound was not administered or cell that was not contacted with the test compound, respectively, indicates that the test compound inhibits infection by HIV."
(emphasis added)

19. A method for testing or determining the efficiency of a test vaccine against HIV, comprising administering to a transgenic rat of claim 1, a vaccine, infecting the transgenic rat with HIV, and determining the level of HIV or gene product thereof, wherein the presence of less HIV or product thereof in a rat having been administered the vaccine relative to a transgenic rat that has not received the vaccine indicates that the test vaccine is efficient.
(emphasis added)

Group IV claim 18 requires:

> **"18. A method for identifying a compound which reduces infection of a human cell by HIV, comprising**
> **(a) administrating a test compound to a transgenic rat of claim 1; and**
> **(b) determining the presence of at least one symptom characteristic of AIDS in the transgenic rat,**
> **wherein the reduction of at least one symptom of HIV in the transgenic rat of step (a) relative to that in a transgenic rat to which the test compound was not administered, indicates that the test compound inhibits infection by HIV."**
> **(emphasis added)**

Group V claim 20 requires:

> **"20. An assay for identifying a test compound, which interferes with a lentivirus ligand-CD4 receptor interaction, comprising the steps of:**
> **(a) incubating a cell of the transgenic rat of claim 3 with a lentivirus ligand and the test compound; and**
> **(b) determining the level of interaction between the lentivirus ligand and CD4 receptor expressed on the cell of the transgenic rat, wherein a difference in the level of interaction relative to that of a cell that was not contacted with the test compound indicates that the test compound interferes with the lentivirus ligand and the CD4 receptor."**
> **(emphasis added)**

It is apparent from comparison of claims 1, 3, 12, 14, 18, 19 and 20 that the subject matter of the claims of Groups II, III, IV and V include as common subject matter a transgenic rat as recited in Group I claims, as a subject used in an assay or method or as a source of cell material used in such assay or method.

The Examiner's attention is directed in this respect to the provisions of MPEP Section 802.01 (Meaning of "Independent" and "Distinct"), which states, *inter alia*:

> **"The term 'independent' (i.e., not dependent) means that there is no disclosed relationship between the two or more subjects disclosed, that is, they are unconnected in design, operation, or effect..."**

It is apparent from this provision of the MPEP that the subject matter of Group I claims 1,3 and the subject matter of claims of Groups II-V are not "independent" within the meaning of 35 USC 121 since they CANNOT BE CHARACTERIZED as being "unconnected in design, operation or

effect." The restriction requirement applied against Groups I-V therefore is improper under MPEP Section 802.01, and the claims of Groups I-V are NOT properly restricted.

Based on all the foregoing, it is requested that the restriction requirement be withdrawn.

Further, it is pointed out that the subject matter of the respective claims imposes no serious burden of searching on the Examiner, since (i) Groups II-V together contains only ten additional claims, (ii) all of the Groups II-V assay/method claims require a Group I rat as a subject or a source of cells for such assay/method, and there will therefore be a common nexus of reference material for the respective claims groups, and (iii) the predecessor patents issued on the parent and grandparent applications of the instant application (U.S. Patent 6,660,904 and U.S. Patent 6,156,952, respectively) have each issued with rat and assay/methodology claims, thereby evidencing that such claims of such type should be unitarily examined and prosecuted.

According to the MPEP section 803:

> **"[I]f the search and examination of an entire application can be made without serious burden, the examiner must examine it on the merits, even though it includes claims to independent or distinct inventions." MPEP §803.**

Under the applicable criterion of this MPEP provision, the Examiner is respectfully requested to submit all claims 1-21 to examination on the merits.

Petition for Extension of Time and Fees Payable

Petition hereby is made under the provisions of 37 C.F.R. §1.136(a) for a three (3) month extension of time for response to the December 14, 2005 Office Action in this application, extending the shortened statutory period for reply from January 14, 2006 to April 14, 2006.

The fee of $510.00 specified in 37 C.F.R. §1.17(a)(3) for such three (3) month extension is authorized to be charged in the attached credit card authorization form. Authorization also is hereby given to charge any additional fee or amount properly payable in connection with this extension request to Deposit Account No. 08-3284 of Intellectual Property/Technology Law.